



Patent
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In re the Application of)	
)	
SUBRAMAN R. CHERUKURI, ET AL.)	Art Unit: 1761
)	
Serial No.: 09/389,339)	Examiner: A. Corbin
)	
Filed: September 2, 1999)	
)	
Title: MEDICATED CHEWING GUM)	Atty. Dkt. No. 6296.170
DELIVERY SYSTEM FOR)	
NICOTINE)	

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

DECLARATION

Dear Sir:

Edward J. Cone, declares and states that:

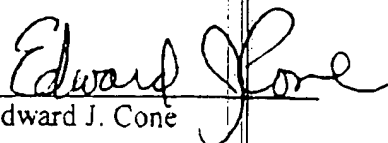
1. I am one of the named inventors herein, and I am making this Declaration pursuant to 37 C.F.R. § 132 in order to submit for consideration evidence obtained during tests conducted upon prototype nicotine gums produced pursuant to the disclosure and claims hereof.
2. As explained during the interview of December 6, 2000, the attached graph illustrates a comparison between a 2 gram Nicorette ® sample having a sodium buffer and two 2 gram samples of prototype gums having a potassium buffer. One prototype sample, designated Ed NIC-01, had nicotine polacrilex as the active, and the other prototype sample, designated Ed NIC-05, had nicotine salt as the active. Nicorette has nicotine polacrilex as the active ingredient.

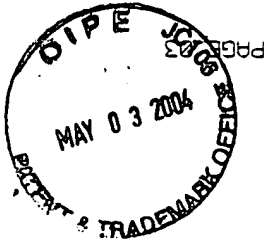
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3. The graph illustrates the percentage of available nicotine released from the respective samples over a thirty (30) minute interval during "chew out" tests that were conducted under what were believed to be uniform conditions.
4. The graph illustrates that the samples pursuant to the invention released higher percentages of their nicotine as compared to Nicorette during the first few minutes of chewing, and that they thereafter released the nicotine at a relatively constant sustained rate thereafter.
5. The Nicorette sample, on the other hand, released its nicotine at a relatively slow and relatively constant rate throughout the test period.
6. The graph indicates that within the first two (2) minutes, the samples produced pursuant to the application released 20.0 % and 26.8 % of their available nicotine, and that Nicorette released 5.8 %.

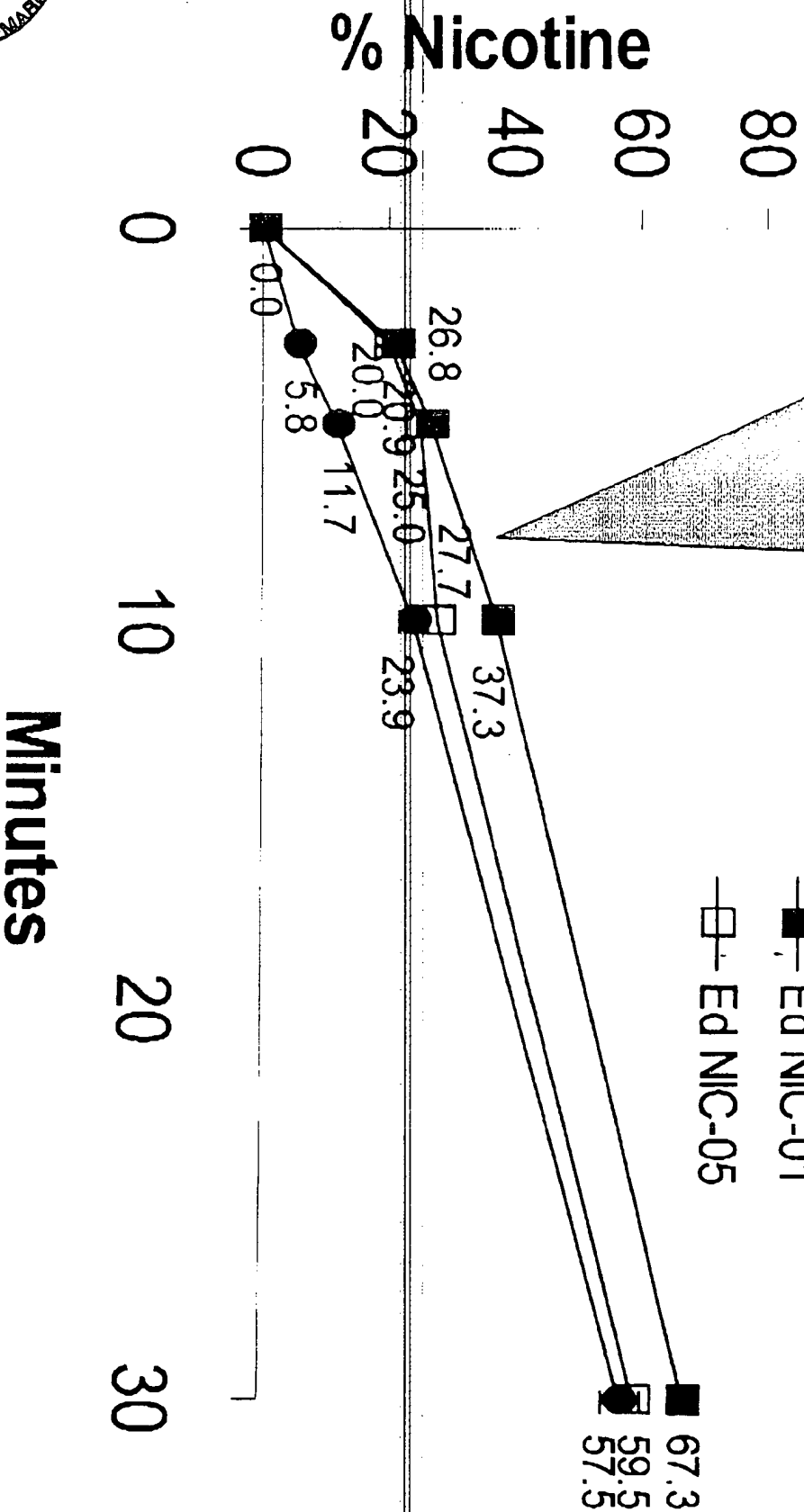
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U. S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any resulting patent issued thereon.

Dated:


Edward J. Cone



Illustrates change from Nicorette (constant release) to hydrophilic Base A produces bi-phasic release for PC and NS (slower sustained release)



Nicorette (2PC/SB/20NaC-10NaHC)
v. NIC-01 (2PC/55A/20KC-10KHC)
v. NIC-05 (2NS/55A/20KC-10KHC)